REMARKS

By this Amendment, Applicants have amended claims 1 and 10 to more clearly define their invention. In particular, Applicants have amended the claims to clarify that at least one measurement value is related to heat measurement. See, e.g., page 3, line 9 to page 4, of Applicants' specification.

Claims 1, 3, 4 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,269,314 to Iitawaki et al. in view of U.S. Patent No. 5,924,996 to Cho et al. Applicants traverse this rejection and request reconsideration thereof.

The present invention is characterized by "a selecting means for selecting an able-bodied person or a diabetic patient" and "a calculating portion for calculating a blood sugar level based on the plurality of measurement values obtained in the measuring portion and the result of selection by the selecting means" (see Claim 1).

The invention is based on the following model created on the premise that body temperature is determined by the balance between the amount of energy produced by glucose combustion in the body, namely, heat production, and heat dissipation:

(1) The amount of heat production and the amount of heat dissipation are considered equal.

(2) The amount of heat production is a function of the blood glucose concentration and the volume of oxygen supply.

(3) The volume of oxygen supply is determined by the blood hemoglobin concentration, the blood hemoglobin oxygen saturation, and the volume of blood flow in the capillary blood vessels.

(4) The amount of heat dissipation is mainly determined by heat convection and heat radiation.

(5) The relationship between the blood glucose level and the amount heat produced varies between diabetic patient and able-bodied person.

In accordance with this model, blood sugar levels can be accurately determined by thermally measuring the body surface and simultaneously measuring parameters relating to the oxygen concentration in the blood and to the blood flow volume, and then using the results of these measurements.

Item (5) of the model, i.e., the relationship between the blood glucose level and the amount heat produced varies between diabetic patient and able-bodied person, is a particularly new insight. If a common regression function determined from groups of measurement data involving both diabetic patients and able-bodied persons is used without taking into consideration the difference between them, the correlation coefficient with the glucose concentration determined by the enzymatic electrode method could possibly become smaller. Thus, separate regression functions are determined for diabetic patients and able-bodied persons based on the individual groups of data for diabetic patients and able-bodied persons, so that either a diabetic patient or an able-bodied person can be selected and the corresponding regression function can be utilized. In this way, blood sugar levels can be measured with greater accuracy.

The invention is based on the above analysis and, based on the aforementioned features, can provide the effect that "higher accuracy of measurement can be achieved than in the case of measurement conducted by using a common regression function obtained from a measurement data group of a subject group consisting of diabetic patients and able-bodied persons." See, page 3, line 9

to page 4, line 20; page 17, line 12 to page 18, line 2; and the last paragraph on page 24 of Applicants' specification.

Iitawaki et al. discloses a data input device 3 as to device to measure blood sugar (Column 4, lines 7-10). Data inputted into the device are disclosed as data from an invasive-type blood sugar meter, data from an invasive-type blood sugar measurement device, and data concerning when the patient ate or how much he exercised (Column 4, lines 11-27). Then, as to the data calculation performed by blood sugar calculation unit, they disclose that the data needed to measure the blood sugar value accurately is to be blood sugar value, and the diabetic state of the patient or the state of the patient relating to another physical condition which might affect blood sugar levels, etc. (Column 5, lines 1-10). Here, they show that the patient's diabetic state plays a large role in how the blood sugar level changes (Column 5, lines 42-46).

However, the data calculation shown by Iitawaki et al. is completely different from the present invention. Iitawaki et al's calculation is based on a prediction made by using the previous blood sugar reading as the central value and making a distribution, and is quite different from the present invention. As the consideration of the severity of the diabetes, Iitawaki et al. disclose the use of time coefficient varied with the severity of the diabetes in calculating "$\mu=\mu+$amount of food eaten x time coefficient" for the patient who has eaten between the time of the previous measurement and the present where μ and σ are the most recent blood sugar value and the distribution determined by using the time which has elapsed since the last measurement as a basis, respectively (Column 5, lines 53-60). On the contrary, the present invention is based on the model described above (in which "(5) The relationship between the blood glucose level and the amount heat produced varies

between diabetic patient and able-bodied person" is a particularly new insight) and calculates based on the plurality of measurement values related to a body surface and a measurement environment, including at least a measurement value related to heat measurement, and the result of selection by the selecting means. Iitawaki et al. do not disclose "a selecting means for selecting an able-bodied person or a diabetic patient," one characteristic of the present invention. Thus, the result of selection by the selecting means, that is, the input of information whether an able-bodied person or a diabetic patient is not suggested by Iitawaki et al. Moreover, Iitawaki et al. need the input of the blood sugar value itself. Therefore, the base for the calculation is completely different between Iitawaki et al. and the present invention.

The patent to Cho et al. discloses a processing device for sensing the thermal interaction between the human the disclosed device. They thus obtain physical measurements are electronically converted and may be associated in an appropriate manner to concentrations of certain components of human blood determined in an unambiguous manner, such as glucose. However, the Cho et al. patent does not disclose an apparatus including selecting means for selecting an able-bodied person or a diabetic patient or a method including obtaining a type identifying an able-bodied person or a diabetic patient. Moreover, the Cho et al. patent does not disclose a calculation portion for calculating a blood sugar level based on, inter alia, the result of selection by the selecting means or a method including calculating a blood sugar level using, inter alia, a regression function for either able-bodied persons or diabetic patients chosen based on the obtained identifying an able-bodied person or a diabetic patient.

Thus, even assuming, arguendo, one of ordinary skill in the art would have used the device of Cho et al. in the system of Iitawaki et al., one would not arrive that

the presently claimed apparatus or method. That is, even the proposed combination of Iitawaki et al. and Cho et al. would not have suggested the apparatus presently claimed, including the presently claimed selecting means and calculation portion, or the method presently claimed, including obtaining a type identifying an able-bodied person or a diabetic patient, and calculating a blood sugar level using, inter alia, a regression function for either able-bodied persons or diabetic patients chosen based on the obtained type identifying an able-bodied person or a diabetic patient. Accordingly, claims 1-3 and 10 are patentable over the proposed combination of Iitawaki et al. and Cho et al.

Claim 2 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Iitawaki et al. in view of Cho et al. and further in view of U.S. Patent No. 6,322,504 to Kirshner. Applicants traverse this rejection and request reconsideration thereof.

The deficiencies of Iitawaki et al. and Cho et al. are noted above.

The patent to Kirshner relates to interactive computerized method and system for determining for the risk of developing a disease, consequences of the disease, providing ways of modifying the risk, and tracking the progress of an individual as his or her risk factors change or remain the same. It is disclosed the user's medical history is collected and stored, for example, in a medical history database. For example, the user is queried whether the user has diabetes mellitus and, if so, the user is prompted to enter, if known, his or her blood fasting sugar, whether the user is taking insulin, hypoglycemics or neither insulin nor hypoglycemics. If the user is taking insulin, the user is prompted his or her NPH and/or regular dose. However, there is absolutely no suggestion in Kirshner that this information should be used for measuring blood sugar level. To the contrary, the user is prompted to enter his or her blood fasting sugar. Accordingly, the Kirshner does not remedy any of the

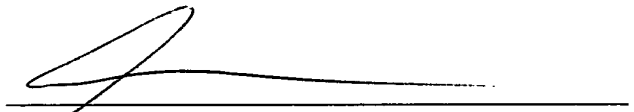
deficiencies noted above with respect to Iitawaki et al. and Cho et al. Therefore, claim 2 is patentable over the proposed combination of references.

Applicants note the indication of allowable subject matter in claims 5-9 and 11. In view of the foregoing amendments, it is submitted all of the claims now in the application are in condition for allowance.

To the extent necessary, applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to the deposit account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (Case: 1021.43510X00), and please credit any excess fees to such deposit account.

Respectfully submitted,

ANTONELLI, TERRY, STOUT & KRAUS, LLP



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